Amendment No. 1 to HB2661

Kumar
Signature of Sponsor

**AMEND Senate Bill No. 2458* House Bill No. 2661**

by deleting all language after the enacting clause and substituting:

SECTION 1. Tennessee Code Annotated, Section 56-7-3102 is amended by deleting the section and substituting:

As used in this part, unless the context otherwise requires:

(1) "Covered entity":

(A) Means an individual or entity, other than a patient, healthcare provider, or pharmacist, involved in the financing of a pharmacy benefits plan or program; and

(B) Does not include:

(i) The TennCare program administered pursuant to the waivers approved by the United States department of health and human services;

(ii) The sponsor of a plan subject to regulation under medicare part D (42 U.S.C. §§ 1395w–101, et seq.); or

(iii) A health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, medicare supplement, disability income, or other long-term care;

(2) "Maximum allowable cost list" means a listing of pharmaceutical products or method for calculating reimbursement amounts used by a pharmacy benefits manager, directly or indirectly, setting the maximum allowable cost on which reimbursement payment to a pharmacy or pharmacist may be based for

dispensing a prescription pharmaceutical product and includes, but is not limited to:

(A) Average acquisition cost, including national average drug acquisition cost;

(B) Average manufacturer price;

(C) Average wholesale price;

(D) Brand effective rate or generic effective rate;

(E) Discount indexing;

(F) Federal upper limits;

(G) Wholesale acquisition cost; and

(H) Any other term that a pharmacy benefits manager or a third-party payor may use to establish reimbursement rates to a pharmacist or pharmacy for pharmaceutical products;

(3) "Pharmaceutical product" means a generic drug, brand-name drug, biologic, or other prescription drug, vaccine, or device;

(4) "Pharmaceutical wholesaler":

(A) Means an individual or entity that sells and distributes, directly or indirectly, prescription pharmaceutical products, including, but not limited to, brand-name, generic, and over-the-counter pharmaceuticals, and that offers regular or private delivery to a pharmacy; and

(B) Includes a prescription pharmaceutical product manufacturer that sells directly to a pharmacy or pharmacist;

(5) "Pharmacist" has the same meaning as defined in § 63-10-204;

(6) "Pharmacy" has the same meaning as defined in § 63-10-204;

(7) "Pharmacy acquisition cost" means the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice;

(8) "Pharmacy benefits manager" means an individual or entity that administers or manages a pharmacy benefits plan or program on behalf of a covered entity;

(9) "Pharmacy benefits manager affiliate" means a pharmacy or pharmacist that directly or indirectly, through one (1) or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager;

(10) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmaceutical products to individuals who reside in or are employed in this state; and

(11) "Pharmacy services administrative organization" means an entity that provides contracting and other administrative services to a pharmacy to assist in the pharmacy's interaction with third-party payers, pharmacy benefits managers, drug wholesalers, and other entities.

SECTION 2. Tennessee Code Annotated, Section 56-7-3104, is amended by deleting the section and substituting:

(a) Notwithstanding another law to the contrary, a pharmacy benefits manager shall not place or continue to list a pharmaceutical product on a maximum allowable cost list unless the pharmaceutical product:

(1) Is generally available for purchase by pharmacies in this state from national or regional wholesalers operating in this state; and

(2) Is not obsolete.

(b) Notwithstanding another law to the contrary, a pharmacy benefits manager shall:

(1) Provide access to its maximum allowable cost list to each pharmacy subject to the maximum allowable cost list;

(2) Update its maximum allowable cost list on a timely basis, but in no event more than three (3) calendar days after the date of:

(A) An increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in this state; or

(B) A change in the methodology on which the maximum allowable cost list is based or in the value of a variable involved in the methodology; and

(3) Provide a process for each pharmacy subject to the maximum allowable cost list to receive notification within three (3) calendar days of an update to the maximum allowable cost list.

(c)

(1) A pharmacy benefits manager shall provide a reasonable appeal procedure to allow a pharmacy to challenge maximum allowable costs and reimbursements made under a maximum allowable cost list for a specific pharmaceutical product or pharmaceutical products as:

(A) Violating this section; or

(B) Being less than the pharmacy acquisition cost.

(2) The reasonable appeal procedure required pursuant to this subsection (c) must include the following:

(A) A dedicated telephone number and email address or website for the purpose of submitting appeals;

(B) The ability to submit an appeal directly to the pharmacy benefits manager regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization; and

(C) Provide no less than seven (7) business days to file an appeal.

(3) A pharmacy benefits manager shall respond to an appeal under this subsection (c) within seven (7) business days after notice of the appeal is received by the pharmacy benefits manager.

(4)

(A) If a pharmacy benefits manager grants an appeal under this subsection (c) by finding that this section has been violated or the pharmacy or pharmacist was reimbursed less than the pharmacy acquisition cost, then within seven (7) business days after notice of the appeal is received by the pharmacy benefits manager, the pharmacy benefits manager shall:

(i) Make the necessary change to the challenged maximum allowable cost;

(ii) Permit the challenging pharmacy or pharmacist to reverse and rebill the claim upon which the appeal is based;

(iii) If the pharmaceutical product involved in the appeal is a drug, then provide to the pharmacy or pharmacist the national drug code number for the drug on which the increase or change is based; and

(iv) Make the change effective for each similarly situated pharmacy that is subject to the maximum allowable cost list.

(B) If a pharmacy benefits manager denies an appeal under this subsection (c), then within seven (7) business days after notice of the appeal is received by the pharmacy benefits manager, the pharmacy benefits manager shall provide the appealing pharmacy or pharmacist with:

(i) The name of the national or regional pharmaceutical wholesalers operating in this state that have the pharmaceutical

product currently in stock at a price that is less than the cost listed on the maximum allowable cost list; and

(ii) If the pharmaceutical product involved in the appeal is a drug, then the national drug code number for the drug. If the pharmaceutical product involved is a medical device, then the unique device identifier for the device.

(C) If the pharmaceutical product associated with the national drug code number or unique device identifier is not available at a cost that is less than the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription pharmaceutical products for resale, then the pharmacy benefits manager shall adjust the maximum allowable cost to an amount greater than the appealing pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the pharmaceutical product at a cost that is equal to or less than the previously challenged maximum allowable cost.

(d) It is the intent of this section that each pharmacy or pharmacist in this state be reimbursed an amount by a pharmacy benefits manager that is not in violation of this section or below the pharmacy or pharmacist's pharmacy acquisition cost. The commissioner of commerce and insurance is authorized to promulgate rules to effectuate the purposes of this section, including, but not limited to, an external appeals process for any claim denied by a pharmacy benefits manager. If the commissioner does institute an external appeals process pursuant to this subsection (d), then all expenses associated with the external appeals process must be paid from the department of commerce and insurance's existing resources. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(e) A pharmacy benefits manager shall not reimburse a pharmacy or pharmacist an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmaceutical product. The amount must be calculated on a per unit basis based on the same generic product identifier or generic code number.

(f) A pharmacy or pharmacist may decline to provide a pharmaceutical product to a patient or pharmacy benefits manager if, as a result of a maximum allowable cost list, the pharmacy or pharmacist would be paid less than the pharmacy acquisition cost of the pharmacy providing the pharmaceutical product.

SECTION 3. Tennessee Code Annotated, Section 56-7-3106, is amended by deleting the section and substituting:

A pharmacy benefits manager shall pay a pharmacy dispensing a pharmaceutical product pursuant to a pharmacy benefits agreement a professional dispensing fee at a rate not less than the amount paid by the TennCare programs administered pursuant to the waivers approved by the United States department of health and human services, as set forth in the operative edition of the Division of TennCare Pharmacy Provider Manual, or successor publication, for each prescription pharmaceutical product that is dispensed to the patient by the pharmacy. The dispensing fee required to be paid pursuant to this section must be calculated on a per unit basis based on the same generic product identifier or generic code number. The dispensing fee is in addition to the amount that the pharmacy benefits manager reimburses a pharmacy, consistent with this part, for the cost of the pharmaceutical product that the pharmacy dispenses to the patient.

SECTION 4. Tennessee Code Annotated, Section 56-7-3107, is amended by deleting the section and substituting:

A pharmacy benefits manager shall not assess, charge, or collect any form of remuneration that passes from a pharmacy or pharmacist to the pharmacy benefits

manager, including, but not limited to, claim-processing fees, performance-based fees, network-participation fees, or accreditation fees.

SECTION 5. Tennessee Code Annotated, Section 56-7-3108, is amended by deleting the section and substituting:

A pharmacy benefits manager shall not directly or indirectly deny or reduce a claim after the claim has been processed, unless one (1) of the following applies:

(1) The original claim was submitted fraudulently; or

(2) The original claim payment was incorrect because the pharmacy or pharmacist had already been paid for the pharmaceutical product.

SECTION 6. Tennessee Code Annotated, Section 56-7-3115, is amended by deleting the section and substituting:

(a) A pharmacy benefits manager shall allow participants and beneficiaries of the pharmacy benefits plans and programs that the pharmacy benefits manager serves to utilize any pharmacy within this state that is licensed to dispense the prescription pharmaceutical product that the participant or beneficiary seeks to fill, as long as the pharmacy is willing to accept the same terms and conditions that the pharmacy benefits manager has established for at least one (1) of the networks of pharmacies that the pharmacy benefits manager has established to serve patients within this state.

(b) A pharmacy benefits manager may establish a preferred network of pharmacies and a non-preferred network of pharmacies, but the pharmacy benefits manager shall not prohibit a pharmacy from participating in either type of network within this state as long as the pharmacy is licensed by this state and the federal government and willing to accept the same terms and conditions that the pharmacy benefits manager has established for other pharmacies participating within the network that the pharmacy wishes to join.

(c) A pharmacy benefits manager shall not charge a participant or beneficiary of a pharmacy benefits plan or program that the pharmacy benefits manager serves a

different copayment obligation or additional fee, or provide any inducement or financial incentive, for using any pharmacy within a given network of pharmacies established by the pharmacy benefits manager to serve patients within this state.

SECTION 7. Tennessee Code Annotated, Section 56-7-3206, is amended by deleting the section and substituting:

A violation of this part may subject the pharmacy benefits manager or covered entity to the sanctions described in § 56-2-305.

SECTION 8. Tennessee Code Annotated, Section 4-3-1021(c)(3), is amended by deleting the subdivision.

SECTION 9. Tennessee Code Annotated, Section 56-7-1013(g)(2)(C), is amended by deleting the language "56-7-3106" and substituting instead the language "56-7-3104".

SECTION 10. This act takes effect thirty days after becoming a law, the public welfare requiring it, and:

(1) Section 7 applies to all actions occurring on or after the effective date of this act; and

(2) All other Sections apply to:

(A) All pharmacy benefits plan and program payments made on or after July 1, 2021, but prior to the effective date of this act, by a pharmacy benefits manager for the period in which the pharmacy benefits manager did not have an approved actual reimbursement appeals process;

(B) All pharmacy benefits plan and program payments made on or after the effective date of this act; and

(C) All other pharmacy benefits plans and programs entered into, renewed, or otherwise modified after the effective date of this act.